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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Docket Number (Optional) PRE-APPEAL BRIEF REQUEST FOR REVIEW 05899-00013-US Application Number Filed January 7, 2002 09/914,006-Conf. #7184 First Named Inventor Lothar Eggeling et al. Art Unit Examiner 1652 C. L. Fronda Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant /inventor. assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) Liza D. Hohenschutz is enclosed. (Form PTO/SB/96) Typed or printed name x attorney or agent of record. 33,712 Registration number (302) 658-9141 Telephone number attorney or agent acting under 37 CFR 1.34. August 25, 2008 Registration number if acting under 37 CFR 1.34. Date NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*. *Total of 1 forms are submitted.

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REMARKS ACCOMPANYING REQUEST FOR PRE-APPEAL BRIEF REVIEW

Claims 14-18, 20-26, 29-37, 40, and 41 are pending in the instant application.

In the Advisory Action mailed August 7, 2008 the Examiner maintained the rejection of claims 14-18, 20-26, 29-37, 40, and 41 on the ground of nonstatutory obviousness-type double patenting over claims 1-25 of U.S. patent No. 6,177,264 (the '264 patent) for the reasons of record.

Applicants respectfully request a Pre-Appeal Brief Review of the foregoing rejection of claims 14-18, 20-26, 29-37, 40, and 41, withdrawal of the rejection and a Notice of Allowance.

In the Office Action mailed March 25, 2008, the Examiner maintained the rejection of claims 14-18, 20-26, 29-37, 40, and 41 on the ground of nonstatutory obviousness-type double patenting over claims 1-25 of U.S. patent No. 6,177,264 (the '264 patent). See Office Action mailed March 25, 2008, pages 2-3 (paragraphs 2-3). Briefly, the Examiner alleged that Examples 1-8 of the '264 patent provide support for the claims of the '264 patent, and used the disclosures of Examples 1-8 to reject claims 14-18, 20-26, 29-37, 40, and 41 as obvious variations of the invention claimed in the '264 patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970) was cited in support of the use of the specification to determine whether a claim in an application defines an obvious variation of an invention claimed in a patent.

Applicants submit that the Examiner has applied an improper standard for determining nonstatutory obviousness-type double patenting, and the rejection should be withdrawn.

In determining whether a nonstatutory basis exists for a double patenting rejection, the <u>claims</u> of the application and the <u>claims</u> of the patent are compared to determine whether the claims of the application are merely an obvious variation of an invention claimed in the patent. Moreover, when considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of

the patent may not be used as prior art. General Foods Corp. v. Studiengesellschaft Kohle GmbH, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992).

According to *In re Vogel*, the prohibition on using the disclosure of the patent as prior art does not mean it may not be used at all. In certain circumstances it may used as a dictionary to learn the meaning of terms in a claim. It may also be used as required to answer the question of what is or is not an obvious variation of a claim. On this point *In re Vogel* states:

We recognize that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim. A claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined. *Id.*, at 622.

In re Vogel allows the comparison of a <u>tangible embodiment of the claimed invention</u> disclosed in the patent with the claims of the application to judge whether the tangible embodiment has been modified in an obvious manner. In re Vogel does not sanction the wholesale use of the disclosure of the patent under the guise that it pertains to the claimed invention. Such an interpretation would render meaningless the prohibition on using the disclosure of the patent as prior art, as most of the disclosure in a patent pertains to the claimed invention in some manner.

The Examiner has impermissibly used the disclosures of the '264 patent as prior art to reject claims 14-18, 20-26, 29-37, 40, and 41. In the response filed June 25, 2008, Applicants provided detailed arguments pointing out the deficiencies in the Examiner's position; see the "Response to Final Action under 37 CFR 1.116" filed June 25, 2008, at pages 3-7.

Although examples 1-8 of the '264 patent disclose materials such as the ilvD, ilvBN, and ilvC genes, an ilvA deletion mutant of *C. glutamicum* and an inactivated panC mutant of *C. glutamicum*, that may also be used with some of the microorganisms and methods of the present application, such materials are not claimed in the '264 patent, nor do they represent tangible embodiments of the invention claimed in the '264 patent. The portion of the specification that can be used in the double patenting analysis should be limited to specific disclosures in Examples 1 and 4, and, possibly Examples 7 and 8. The remaining portions of Examples 1, 4, 7 and 8, and Examples 2, 3, 5 and 6 do not disclose specific embodiments of the invention claimed in the '264 patent and cannot be used in the double patenting analysis because to do so would be impermissibly using them as prior art against the present claims.

Claims 14-17 and 41 of the present application are directed to a microorganism transformed with a nucleotide sequence encoding dihydroxy acid dehydratase (ilvD), nucleotide sequences encoding acetohydroxy acid synthase and isomeroreductase (ilvBNC) or both ilvD and ilvBNC, in which microorganism the activity of one or more enzymes that are specifically involved in the synthesis of D-pantothenate is reduced or eliminated, wherein the one or more enzymes are selected from the group consisting of ketopantoate hydroxymethyl transferase (panB), pantothenate ligase (panC), ketopantoic acid reductase (panE) and aspartate decarboxylase (panD) and the activity of the one or more enzymes is reduced or eliminated as a result of deletion of all or a part of the nucleotide sequence encoding the enzyme in the microorganism, and wherein the microorganism is a *Corynebacterium* species and the nucleotide sequence encoding ilvD comprises the portion of SEQ ID NO: 1 encoding ilvD.

Claims 10 and 11 of the '264 patent, which are directed to microorganisms, require a vector comprising a nucleotide sequence encoding panB or panC. (The transformed microorganisms used in the methods of claims 12-20, 24 and 25 require transformation with a vector comprising a nucleotide sequence encoding panB and panC.)

The microorganisms of claims 14-17 and 41 are not identical to the microorganisms of claim 10 or 11 of the '264 patent. Additionally, claims 14-17 and 41 are not obvious variations of claims 10 and 11 because there is no equivalent to the vector comprising a nucleotide

sequence encoding panB or panC. The microorganisms of claims 10 and 11 of the '264 patent contain at least one nucleotide sequence encoding panB or panC in addition to the native sequence(s). By contrast, the transformed microorganisms of claims 14-17 and 41 contain only native panB and/or panC sequences, or the native panB and/or panC sequences have been partially or completely deleted.

Claims 18, 20-26, 29-37 and 40 of the present application are not identical to the methods of claims 12-25 of the '264 patent. Claims 18, 20-26, 29-37 and 40 are directed to methods of producing L-valine. Claims 12-25 of the '264 patent, however, are directed to methods for producing pantothenate, a different substance. Additionally, claims 18, 20-26, 29-37 and 40 are not obvious variations of claims 12-15 of the '264 patent. Pantothenate and L-valine have very different structures, and methods of preparing one could not in any way be considered the equivalent or suggestive of the other.

When the correct standard is applied in the instant rejection, it is clear that claims 14-18, 20-26, 29-37, 40, and 41 are not obvious variations of claims 1-25 of the '264 patent. Claims 14-18, 20-26, 29-37, 40, and 41 are patentably distinct from claims 1-25 of the '264 patent. Withdrawal of this double patenting rejection is respectfully requested.